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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/402,845	Applicant(s) Laus et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 17, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4, and 23-26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4, and 23-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Amendment filed December 17, 2002 (Paper No. 15) in response to the Office Action of June 17, 2002 (Paper No. 13) is acknowledged and has been entered. Previously pending claims 2, 3, 5-22 have been canceled, claim 1 has been amended and new claims 23-26 have been added. Claims 1, 4 and 23-26 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following objections are maintained:

Objection to the Specification in Paper No. 13, Section 2, page 2 is maintained because Applicant has neither corrected the objected to material nor distinctly and specifically point out the supposed errors in the objection.

4. The following rejections are maintained:

Claim Rejections - 35 USC § 102

5. Claims 1 and 4 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 13, Section 11, pages 9-10.

Applicant argues that (a) Iype et al do not disclose mouse PAP having the sequence of SEQ ID NO:2, (b) do not disclose the use of xenogeneic form of PAP having the sequence of SEQ ID NO:2 to induce an immune response in a subject.

The argument has been considered but has not been found persuasive because (a') as previously set forth, the mouse PAP of Iype appears to be the same as the claimed mouse PAP, absent a showing of unobvious differences. Applicant has not met the burden of proving that the claimed PAP is physically or functionally different than that taught by the art or to establish patentable differences, (b') neither

claim 1 nor claim 4 is drawn to the use of xenogeneic form of PAP having the sequence of SEQ ID NO:2 to induce an immune response in a subject.

New Grounds of Objection

6. The amendment filed December 17, 2002 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the incorporation by reference of the parent cases of the instant application. MPEP 201.06(c) specifically states that:

> A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).
>
> Applicant is required to cancel the new matter in the response to this Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claims 1, 4, 23-26 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The

limitation of an isolated polypeptide which is immunoreactive with an antibody that is itself immunoreactive with human PAP comprising an amino acid sequence presented as SEQ ID NO:2, including conservative amino acid substitutions that do not alter the sequence by more than 10%, a method of inducing an immune response against human PAP comprising administering an xenogeneic form of PAP from a different mammalian species with is immunoreactive with an antibody that is itself immunoreactive with human PAP wherein said xerographic form of PAP has at least 90% identity with SEQ ID NO:2 has no clear support in the specification and the claims as originally filed. Applicant cites support for the newly claimed limitations on page 9 line 13 to page 10 line 13 and Example 3. A review of the cited support reveals support for induction of an xenogeneic immune response against human PAP in rats (p. 9, lines 10-16) support for immunizing mice with rat, human or mouse PAP, wherein antibodies were detected that reacted with all three of the antigens (p. 9, line 29-page 10 line 12) and support for immunoresponse in rats and mice immunized with mouse or rat PAP (p. 14, lines 1-12). It is noted that although SEQ ID NO:2 is recited in the specification, SEQ ID NO:2 is specifically defined as "a deduced amino acidsequence for mPAP", thus it is not clear from the specification that it is in particular SEQ ID NO:2 that is referred to on pages 9 and 10 or in Example 3. The suggested support is not found persuasive because there is no nexus between the cited support and SEQ ID NO:2 or a variant of SEQ ID NO:2 which binds antibody to human PAP or a method of producing an immune response with SEQ ID NO:2 or a variant thereof with 90% identity to SEQ ID NO:2. The

subject matter claimed in claims 1, 4, 23-26 broadens the scope of the invention as originally disclosed in the specification.

8. Claims 1, 4, 23-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 23-26 are indefinite because they are confusing, it is not clear from the language of the claims whether the variant of SEQ ID NO:2 is human PAP or whether it is a form of PAP from another species.

Claim Rejections - 35 USC § 102

9. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Roiko et al, (Gene, 1990, 89:223-229), of record or Sharief et al, (BBRC., 1992, 184:1468-1476).

The claim is drawn to an isolated polypeptide which is immunoreactive with an antibody that is itself immunoreactive with hPAP comprising SEQ ID NO:2 wherein the sequence comprises an amino acid sequence presented as SEQ ID NO:2, including conservative amino acid substitutions that do not alter the sequence by more than 10%.

Given the broad claim language, it is assumed for examination purposes that the alterations in the sequence are not limited to only conservative substitutions, only that the alterations are limited to not more than 10% conservative substitutions.

Roiko et al (see attached us-09-402-845-2.rsp result 1) specifically teach a rat PAP comprising less than 10% conservative substitutions as compared with SEQ ID NO:2. Given the identity of rat PAP to human PAP (see us-09-402-845-2.rsp, result

2), it would be expected that a subset of polyclonal antibodies produced against the rat PAP would be immunoreactive with an antibody that is itself immunoreactive with human PAP. All of the limitations of the claim are met.

Sharief et al (see us-09-4020845-2.rsp result 2) specifically teach human PAP comprising less than 10% conservative substitutions as compared with SEQ ID NO:2. It is an inherent property of antibodies against human PAP to be immunoreactive with human PAP. All of the limitations of the claim are met.

Claim Rejections - 35 USC § 103

8. Claims 23-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Iype et al, of record, in view of Johnstone et al, of record and Roiko et al (Gene, 1990, 89:223-229) of record.

The claims are drawn to a method of inducing an immune response against human PAP in a mammalian subject comprising administering to a subject an immunogenic dosage of a compositions comprising a xenogeneic form of PAP which is immunoreactive with an antibody that is itself immunoreactive with human PAP wherein said xenogeneic form of PAP has at least 90% identity to SEQ ID NO:2, is mouse PAP, has the amino acid sequence of SEQ ID NO:2.

Iype et al teach as set forth previously but do not specifically teach a method of inducing an immune response against human PAP in a mammalian subject comprising administering to a subject an immunogenic dosage of a composition comprising a xenogeneic form of PAP which is immunoreactive with an antibody that is itself immunoreactive with human PAP wherein said xenogeneic form of PAP

has at least 90% identity to SEQ ID NO:2, is mouse PAP, has the amino acid sequence of SEQ ID NO:2.

Roiko et al teach the evolutionary conservation of sequence and structure of rat and human prostate acid phosphatase and in particular the conservation of reactive sites between rat and human prostate acid phosphatase (see abstract) and conclude that there is a high degree of conservation of the two enzymes at the amino acid level (p.229, col 1)

Johnstone et al teach as set forth previously, that is conventional antibody production in a goat (p. 30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to induce an immune response, which reads on producing a polyclonal antibody, to the mouse prostatic acid phosphatase of Iype because the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). Although Iype does not characterize the mouse PAP as having the functional property of inducing an immune response against human prostatic acid phosphatase, given the art known conservation of sequence and structure across species for important enzymes and given the demonstration by Roiko et al of the high conservation of identity of rat and human PAP it would have been reasonable to conclude that the mouse PAP of Iype would also have conservation of sequence and structure and that a subset of antibodies produced against the mouse antigen would

also be immunoreactive with human PAP. Further, it would have been *prima facie* obvious and one of ordinary skill in the art would have been motivated to induce the immune response in a mammal to which the mouse prostatic acid phosphatase is xenogeneic because Johnstone et al teach that antibody production in a goat is conventional and one would have a reasonable expectation of success in producing said immune/antibody response.

9. All other objections and rejections recited in Paper No. 13 are withdrawn.

10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar
Primary Patent Examiner
March 3, 2003